

REMARKS

Status of the Claims

Claims 88 and 90-172 are currently pending in the subject application. By this amendment, Claims 90, 98-100, 119, 121 and 167 have been amended, and Claims 88, 97, 127 and 168-172 have been canceled without prejudice or disclaimer. Claims 88 and 168-172 have been withdrawn, and are canceled in this Amendment. Upon entry of this Amendment, Claims 90-96, 98-126 and 128-167 will be pending in the subject application.

Claims 90 and 167 have been amended for clarification purposes and to incorporate the feature of canceled Claim 97. Claims 98-100 have been amended to change their dependencies. Claim 119 has been amended to eliminate reference to corona treatment of the holding chamber, which is claimed in Claim 108. Claim 121 has been amended to specify that a predetermined amount of reagent is added in the holding chamber. No new matter has been added.

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 90-167 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, it has been asserted that in Claim 90, step (d), it is not clear if the sample is moved to a new location positioned near the sensor by the pump or if the sample remains at the position where it was mixed with the reagent. Claim 167 was rejected for similar reasons. Applicants respectfully traverse this rejection in view of amended claims 90 and 167.

A fair reading of the subject application will show that introducing the sample into the holding chamber in step (a) acts as the metering step as any excess fluid passes into the overflow chamber of step (b). Thus, the combination of steps (a) and (b) provide a metered sample volume which is then moved to the analysis location in step (c). The reagent is in the analysis location (optionally coated on the wall) and it is in that location that it is mixed with the sample, as indicated in step (d). Notwithstanding Applicants' traversal of this rejection, in an effort to expedite allowance of the subject application, Applicants have amended Claims 90 and 167 to further clarify that the positioning step occurs after the mixing step.

Claims 108 and 119 stand rejected in that they allegedly do not appear to further limit the method of Claim 90 because they are directed to the method of making the holding chamber and should be deleted. It was also asserted that Claim 119 is improper because this claim could be of identical scope to claim 108 if the at least one surface is the holding chamber. Applicants respectfully disagree. Claims 108 and 119 incorporate all of the limitations of base claim 90 and further require that the holding chamber (Claim 108) or overflow chamber (Claim 119) is corona treated. This constitutes a further limitation to base claim 90. To expedite allowance of the subject application, Claim 119 has been amended to delete reference to corona treatment of the holding chamber, which is claimed in Claim 108.

Claim 120 has been rejected as not appearing to further limit the method of claim 90 because it is directed to the shape/size of the apparatus. Applicants traverse this rejection because Claim 120 includes all of the limitations of base claim 90 and adds the additional limitation that the holding chamber comprises a lower interior-surface-to-volume ratio than the

overflow chamber. Accordingly, Claim 120 further limits the subject matter claimed in base Claim 90. In addition, the claimed “lower interior-surface-to-volume ratio” has inherent process implications on the process claimed in base Claim 90, and in particular, to steps (a) and (b) thereof. Accordingly, it is respectfully submitted that Claim 120 further limits independent Claim 90 from which it depends and is proper. Withdrawal of this rejection is requested.

Claim 121 has been rejected as allegedly not being clear if it is a method or structural limitation. The Examiner has courteously suggested that the claim could be clarified if “adding a predetermined amount or [of] reagent in the holding chamber” were claimed. Claim 121 has been amended herein as suggested, thereby obviating this rejection.

Claim 127 has been rejected as allegedly being unclear what method steps are intended by “the reagent included solubility enhancing components.” By this amendment, claim 127 has been canceled rendering this rejection moot.

Claims 128-129 stand rejected as allegedly not being clear how this further limits the method of Claim 90 and what is the electrochemical species. Applicants respectfully traverse this rejection. The electrochemical species is a molecule that is electroactive, e.g., which can participate in a redox reaction at an electrode. This term is widely understood in the electrochemical art and there is extensive discussion in the section entitled Thrombin-substrate Reaction, starting on page 19, of the subject application. Accordingly, the withdrawal of this rejection is respectfully requested.

Claim 130 stands rejected as allegedly not being clear how this further limits the method of Claim 90 and the locations where the enzyme substrates are located. Applicants respectfully

traverse this rejection. Claim 130 addresses that all the reagent is not necessarily added to the sample from dissolution at a single coating site in the analysis location. This concept is fully described at p. 21, lines 13-20, of the subject application. Claim 130 includes all of the limitations of base Claim 90 and adds the additional limitation that the reagent comprises an enzyme substrate deposited at more than one site within the analysis location. Accordingly, Claim 130 further limits the subject matter claimed in base Claim 90. In addition, the claimed additional limitation has inherent process implications on the process claimed in base Claim 90, and in particular, to step (d) thereof. Accordingly, the withdrawal of this rejection is requested.

Claim 133 stands rejected as allegedly not being clear how this further limits the method of Claim 90, what the matrix is or how dissolution is promoted. Applicants traverse this rejection and direct the Examiner's attention to the section entitled "Reagents" on page 19 of the subject application, which discusses rapid redissolution of dried reagents. From this discussion, one skilled in the art would recognize that various matrix materials (examples of which include the enumerated polymers and gelatin) may be included in the reagent. In addition, Claim 133 includes all of the limitations of base claim 90 and adds the additional limitation that the reagent comprises a matrix that promotes rapid dissolution into the sample. Accordingly, Claim 133 further limits the subject matter claimed in base Claim 90. The withdrawal of this rejection is requested.

Double Patenting

Claims 90-167 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-107 and Claims 1-47 of U.S. Patent Nos.

6,750,053 and 6,438,498, respectively. Applicants assert that this rejection has been obviated in view of the amended claims, and the withdrawal of this rejection is therefore requested.

Rejections Under 35 U.S.C. §§102(b) and 103(a)

Claims 90-104, 107, 109-118, 123, 127, 131-135, 144-145 and 167 stand rejected under 35 U.S.C. §102(b) as being anticipated by Besemer et al. (USP 5,104,813). Claims 90-105, 107, 109-118, 123, 127, 131-135, 144-145 and 167 stand rejected under 35 U.S.C. §102(b) as being anticipated by Handique et al. (USP 6,103,098). Claims 124-126, 136-143 and 146-166 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Besemer et al. or by Handique et al. Applicants respectfully traverse these rejections.

The invention of pending Claim 90 is directed to a method of detecting a reaction product in a sample of blood or blood derivative using a cartridge that includes a holding chamber, an overflow chamber, an analysis location, a pump, a reagent and a sensor, the method comprising the steps of: (a) introducing the sample into the holding chamber in the cartridge; (b) metering a portion of the sample by retaining excess sample in the overflow chamber; (c) moving the metered sample from the holding chamber to the analysis location by means of the pump; (d) mixing the metered sample with the reagent in the analysis location; (e) allowing the reagent to form the reaction product in the sample; (f) after the mixing step, positioning the sample at the sensor in the analysis location using the pump; (g) detecting the reaction product at the sensor; and (h) sealing the holding chamber with a closable sample entry port after step (a). Independent claim 167 is directed to a method of assaying an enzyme in a sample of blood or blood derivative using a cartridge, the method including steps substantially similar to steps (a)-(h) of Claim 90.

Concerning Besemer et al., in contrast to the invention of Independent Claims 90 and 167, and the claims depending therefrom, Besemer et al. fails to teach or suggest positioning the sample at the sensor in the analysis location using the pump.

It is well established that prior art must be considered in its entirety including portions that would lead away from the claimed invention. *W.L. Gore & Associates v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983). The Patent Office's assertion that the claimed invention is obvious over Besemer et al. is improper because it requires wholly disregarding passages from Besemer et al., which expressly teach away from the presently claimed invention. Besemer et al. touts at Col. 2, line 42, that its device "does not require the use of externally generated force (except gravity) to move liquids between its various parts." Clearly, based on this disclosure, one skilled in the art would have no motivation whatever for modifying the Besemer et al. disclosure to arrive at the presently claimed invention.

Besemer et al. also fails to disclose or suggest the feature of dependent Claim 114 of the subject application that "a force provided to the sample by the pump comprises a pneumatic force."

In addition, Claims 90 and 167 have been amended herein to specify that the holding chamber is sealed with a closable sample entry port after step (a). Besemer et al. also fails to teach or suggest this feature of the pending claims.

For these reasons, Applicants assert that the presently claimed invention is novel and nonobvious over Besemer et al., and the withdrawal of this rejection is requested.

Concerning Handique et al., as indicated above, the presently claimed invention requires that the holding chamber is sealed with a closable sample entry port after step (a). Handique et al. fails to teach or suggest this feature of the invention. In addition, Handique et al. fails to teach or suggest the feature of dependent Claim 113, which requires that the pump is in fluidic connection with the overflow chamber.

For these reasons, Applicants assert that the presently claimed invention is novel and nonobvious over Handique et al., and the withdrawal of this rejection is respectfully requested.

Accordingly, pending Claims 90-96, 98-126 and 128-167 are believed to be in condition for allowance over the references of record, and a Notice thereof is respectfully requested.

Should the Examiner have any questions regarding this response or the application in general, the Examiner is urged to contact the Applicants' attorney, Justin L. Krieger, by telephone at (202) 625-3858. All correspondence should continue to be directed to the address given below.

Respectfully submitted,

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